

APPENDIX M: Premarket Notification (510(k)) Summary

Submitted by:	Celleration, Inc. 10250 Valley View Road, Suite 137 Eden Prairie, Minnesota 55344
Contact Person:	David L. Bremseth, Pharm.D. Vice President, Clinical & Regulatory Affairs Celleration, Inc. 952-224-8704 (Phone)
Date of Summary:	January 18, 2005
Device Trade Name:	MIST Therapy™ System 5.1
Common or Usual Name:	Ultrasonic Wound Cleaning Device
Classification Name:	Low Energy Ultrasound Wound Cleaner (21CFR 878.4410)
Predicate Device(s):	<ul style="list-style-type: none">• MIST Therapy System 5.0 (K032378)• V.A.C.® ATS™, mini V.A.C.®, V.A.C.® Freedom™ (K032310)• NeoGen One, Closed Wound Drainage System (K032301)• Blue Sky Versatile 1 Wound Vacuum System (K042134)
Device Description:	MIST Therapy System is a non-contact, low-energy ultrasound device, which utilizes continuous ultrasonic energy to atomize saline and deliver a continuous mist to the treatment site to promote wound healing.
Indication for Use:	The MIST Therapy System produces a low energy ultrasound-generated mist used to promote wound healing through wound cleansing and maintenance debridement by the removal of yellow slough, fibrin, tissue exudates and bacteria.
Substantial Equivalence:	<p>The MIST Therapy device under discussion in this application is identical in design, materials, and function to the previously cleared MIST Therapy System (K032378).</p> <p>Both the MIST Therapy systems and the Powered Suction Pump predicates use mechanical energy to promote wound healing through means such as the removal of infectious material and other wound exudates.</p> <p>Although powered suction pumps use negative pressure to promote healing and MIST Therapy utilizes low energy ultrasound, the performance data provided support the substantially equivalent indication for use for the MIST Therapy System of promoting wound healing.</p>
Testing Summary:	MIST Therapy System was subjected to numerous preclinical, animal, and human clinical studies in support of the updated indications for use. All study results supported the conclusion that the MIST Therapy System promotes wound healing.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 17 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

David L. Bremseth, Pharm.D.
Vice President, Clinical & Regulatory Affairs
Celleration, Inc.
10250 Valley View Road, Suite 137
Eden Prairie, Minnesota 55344

Re: K050129
Trade/Device Name: Celleration MIST Therapy™ System 5.1
Regulation Number: 21 CFR 878.4410
Regulation Name: Low energy ultrasound wound cleaner
Regulatory Class: II
Product Code: NRB
Dated: April 13, 2005
Received: April 14, 2005

Dear Dr. Bremseth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

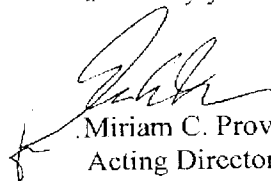
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – David L. Bremseth, Pharm.D.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050129

APPENDIX C: Indications For Use Statement
[As required by 21 CFR 807.92(c)]

510(k) Number: TBD

Device Name: Celleration MIST Therapy™ System 5.1

Indications For Use: The MIST Therapy System produces a low energy ultrasound-generated mist used to promote wound healing through wound cleansing and maintenance debridement by the removal of yellow slough, fibrin, tissue exudates and bacteria.

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



Division of General, Restorative
Dental and Otolaryngological Devices

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